

### Remarks

This Amendment is in response to the Final Office Action dated **January 8, 2008**.

In the Final Office Action, claims 1-9, 11-17, 20 and 22 were rejected under 35 USC §102(e) as being anticipated by Myler et al (5,474,563).

The following comments are presented in the same order, with section headings, as the Office Action.

In the amendment filed October 25, 2007, claim 20 was amended to respond to a 35 USC 112 rejection. In this Amendment, Applicant has amended claim 20 to clarify that, as is recited in independent claims 1 and 12, the ring of the sheath is assisting in the compression of the stent. Applicant requests entry of this Amendment After Final because it places the application in better form for appeal.

#### **35 USC 102(e)**

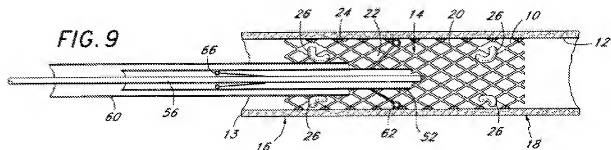
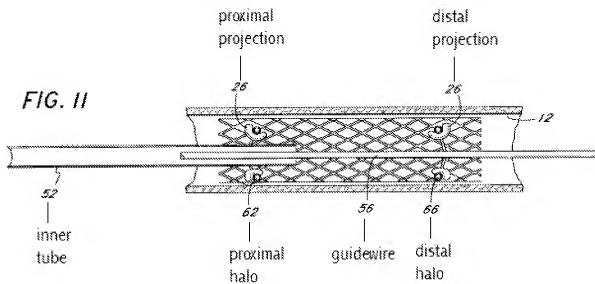
In the Final Office Action, claims 1-9, 11-17, 20 and 22 were rejected under 35 USC §102(e) as being anticipated by Myler et al (5,474,563).

Independent claims 1, 12 and 20 recite, in part, *“the ring assisting in the compression of the stent to the compact transport form from a partially deployed form”* (emphasis added).

The Final Office Action stated:

the distal end of the outer sheath would be capable of assisting in stent compression, if one so desired, by merely retracting the inner members relative to the sheath 60, or moving the sheath distally over the inner members. *As the distal end (ring) of the sheath contacted the stent or the halos, it would cause compression of the stent and allow the stent to be withdrawn into the distal end of the outer sheath 60.* (emphasis added)

Applicant disagrees with this assertion, as discussed below. For reference, Applicant has provided an annotated copy of FIG. 11 of Myler, below. Applicant has also provided a copy of FIG. 9 of Myler which shows the diameter of the sheath 60 relative to the expanded stent.



a. Retracting the Inner Members – Stent Cannot be Withdrawn Into Distal End of the Sheath – Sheath is Not Assisting in the Compression of the Stent to the Compact Transport Form From a Partially Deployed Form

Applicant submits that if the inner members, i.e. halos/spokes 62,63,66,68, are retracted relative to the sheath 60, the stent 10 would not be withdrawn into the distal end of the outer sheath 60, contrary to the assertion in the Final Office Action. As shown in Fig. 9 of Myler, the diameter of the sheath 60 is smaller than the diameter of the stent 10 so that when the sheath 60 is positioned within the lumen of the stent 10, the stent 10 and the projections 26 are positioned about the sheath 60. Therefore, merely retracting the inner members 62,63,66,68 relative to the sheath 60 would not cause the distal end of the sheath 60 to contact the stent 10 and would not cause the stent 10 to be withdrawn into the sheath 60. The smaller diameter of the

sheath 60 in comparison to the larger diameter of the stent 10 is addressed by the stent extraction method described in Myler (see col. 10, line 54 to col. 11, line 3). Therefore, Applicant submits that in this proposed scenario the sheath is not assisting in the compression of the stent to the compact transport form from a partially deployed form.

b. Moving Sheath Distally Over the Inner Members – Sheath is Not Assisting in the Compression of the Stent to the Compact Transport Form From a Partially Deployed Form

Applicant submits that if the sheath 60 is moved distally over the inner members, e.g. halos 62,66 and spokes 63,68, the sheath 60 would first contact the proximal spokes 63. Continued pressure of the sheath 60 against the proximal spokes 63 would result in either i) the proximal halo 62 popping out of the proximal projections 26, or ii) the proximal halo 62 remaining in the proximal projections 26. These two alternative scenarios are discussed below in sections (i) and (ii).

i. The Proximal Halo/Spokes Pop Out of the Proximal Projections – the Stent Remains Within the Vessel – Sheath is Not Assisting in the Compression of the Stent to the Compact Transport Form From a Partially Deployed Form

Myler teaches that *self-expandable stents* are used when the removal catheter, shown in Figs. 9 and 11, is used as an insertion catheter (col. 11, lines 52-54). Thus, even if the stent 10 had decreased in diameter due to the distal movement of the sheath 60 against the proximal halo/spokes 62,63, when the proximal halo/spokes 62,63 pop out of the proximal projections 26, the self-expandable stent 10 would revert back into its implanted diameter. Thus, the stent 10 could not be retracted into the sheath 60 and would remain within the vessel. Therefore, Applicant submits that the sheath is not assisting in the compression of the stent to the compact transport form from a partially deployed form in this scenario.

ii. Proximal Halo Remains in the Proximal Projections

a. Sheath is Withdrawn – Stent Reverts to Expanded Diameter and Remains Within the Vessel – Sheath is Not Assisting in the Compression of the Stent to the Compact Transport Form From a

Partially Deployed Form

Alternatively, if the proximal halo 62 does not pop out of the proximal projections 26, when the sheath 60 advances distally, the sheath 60 will push the proximal spokes 63 in the proximal direction. If the tension of the sheath 60 against the proximal halo/spokes 62,63 causes the proximal spokes 63 to compress the stent 10, Applicant submits that only a portion of the proximal end of the stent 10 would be compressed, e.g. from the proximal end of the stent 10 to the distal edge of the proximal projections 26.

Furthermore, the stent 10 would be compressed inwards towards the outer surface of the sheath 60 since the sheath 60 would be within the stent 10 when it is in contact with the proximal halo/spokes 62,63. Since the sheath 60 would be disposed within the lumen of the stent 10, Applicant submits that the sheath 60 would need to be withdrawn proximally out of the lumen of the stent 10 in order for the proximal end of the stent 10 to be withdrawn into the distal end of the sheath 60. Applicant submits that, without the tension of the sheath 60 against the proximal halo/spokes 62,63, the stent 10 would revert to its expanded diameter when the sheath 60 is withdrawn (see col. 11, line 63 to col. 12, line 2 "Once the stent has been positioned at the treatment site, axial elongating tension is released, and it is permitted to radially expand against the lumen wall. Thereafter the annular halos 62,66 ... are withdrawn within the tubular body, so that they may be proximally withdrawn from within the implanted stent"). Thus, since the stent 10 is once again in its expanded diameter, it cannot be proximally withdrawn into the distal end of the sheath 60, as discussed above in section (a). Because the stent 10 would be in an expanded, implanted state, Applicant submits that the sheath 60 is not assisting in the compression of the stent to the compact transport form from a partially deployed form in this scenario.

b. Proximal Halo/Spokes 62,63 Prevent the Sheath From Contacting the Distal Halo/Spokes 66,68 – Stent Remains Within the Vessel – Sheath is Not Assisting in the Compression of the Stent to the Compact Transport Form From a Partially Deployed Form

If the proximal halo 62 does not pop out of the proximal projections 26, the distal movement of the sheath 60 is limited in part by the length of the proximal spokes 63, which will block any further distal movement of the sheath 60. Myler states that the halo 62 can extend from

about 0.010 inches to about 0.050 inches or greater beyond the outer radius of the tubular body 52 (col. 8, lines 41-43). Applicant notes that since the sheath 60 has a greater diameter than the tubular body 52, the distal movement of the sheath 60 will be less than the length that the halo 62 extends from the tubular body 52. Myler states that the axial length of the stent 10 will typically range from 1 cm (0.4 inches) to about 3-5 cm (1.2 to 2 inches) (col. 6, lines 30-36). Thus, Applicant submits that the proximal halo/spokes 62,63 will prevent the sheath 60 from contacting the distal halo/spokes 66,68. This means that the scenario discussed above in section (ii)(a) would be followed, in which case the sheath is not assisting in the compression of the stent to the compact transport form from a partially deployed form.

Applicant submits that sheath 60 can contact the distal spokes 68 only if the proximal spokes/halo 62,63 pops out of the proximal projections 26. As discussed above in section (b)(i), if the proximal spokes/halo 62,63 pops out of the proximal projections 26, the stent 10 will expand to its implanted diameter, which would prevent withdrawal of the stent 10 into the sheath 60 and subsequent removal of the stent 10 from the vessel. Therefore, Applicant submits that the sheath is not assisting in the compression of the stent to the compact transport form from a partially deployed form.

#### Conclusion

For at least these reasons, the assertion in the Final Office Action that “the distal end of the outer sheath would be capable of assisting in stent compression, if one so desired, by merely retracting the inner members relative to the sheath 60, or moving the sheath distally over the inner members” is not supported by Myler. Therefore, Myler does not anticipate the instant claims. Applicant requests withdrawal of the rejection and submits that claims 1-9, 11-17, 20 and 22 are in condition for allowance.

**Conclusion**

Based on at least the above, Applicant respectfully submits that this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1-9, 11-17, 20 and 22 is requested.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below.

Respectfully submitted,

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